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38263	7590	05/18/2007		
PROPAT, L.L.C. 425-C SOUTH SHARON AMITY ROAD CHARLOTTE, NC 28211-2841			EXAMINER MCCORMICK, MELENIE LEE	
			ART UNIT	PAPER NUMBER
			1655	
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			05/18/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/539,174

Applicant(s)

HABER ET AL.

Examiner

Melenie McCormick

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 and 21-24 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-19 and 21-24 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>06/05 & 04/07</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 05/02/2007 has been entered.

Claim 20 has been cancelled.

Claims 1-19 and 21-24 are presented for examination on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-19 and 21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants have amended claims 1 and 10 such that they now recite the limitation that the instantly claimed cholesterol reducing agent is "further providing a reduction of total cholesterol of at least 10% when said n-3 fatty acid consists of DHA alone. Applicants have pointed to the specification, specifically page 10, lines 1-4 and page 11, lines 19-23, as demonstrating support for the amendment to these claims. Support for this amendment to the claims, however, could not be found in the portions which Applicants pointed to or in any other portion of the specification as originally filed. Therefore, it is not evident that applicants had possession of the invention claimed in claims 1-19 and 21 at the time the application was originally filed.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-19 and 21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The phrase 'n-3 fatty acid comprising at least DHA' in claims 1 and 10 at line 2 renders the claims vague and indefinite. Due to the singular term 'n-3 fatty acid', it is not clear if Applicants are claiming one or more than one n-3 fatty acid. Furthermore, the phrase 'comprising at least DHA' renders the claim indefinite because it is not clear which n-3 fatty acid the claims are drawn to.

All other claims depend directly or indirectly from rejected claims and are, therefore, also rejected under USC 112, second paragraph for the reasons set forth above.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-19 and 21-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Marco et al. (US 5,856,313), Zunft et al. (Advances in Therapy) Breivik et al. (US 5,502,077), and McKenney (Lipid Management).

Marco et al. beneficially teach a carob product which contains insoluble carob fiber (see e.g. col 1, lines 5-10). Marco et al. further beneficially teach that the carob product has a hypocholesterol-aemic effect, which can counteract the effects of modern cholesterol-rich diets (see e.g. col 1, lines 34-39). Marco et al. also disclose that in rats fed a high cholesterol diet, the increase in cholesterol in a test group which was fed the carob fiber product was significantly lower than those fed another type of fiber (see e.g. all of column 5). Therefore, the carob product beneficially taught by Marco et al. would intrinsically have the effect of reducing cholesterol. Marco et al. further teach that the carob product contains 4-8% moisture, which reads on the carob fiber in water, as instantly claimed (see e.g. abstract). Marco et al. do not explicitly teach

that the product additionally contains at least one n-3 fatty acid or at least one cholesterol-reducing active compound or that the carob fiber is present in an amount from 1 to 15 grams.

Zunft et al. beneficially teach that administration of 15 grams of a carob preparation was administered to test subjects and resulted in a reduction in total and LDL cholesterol levels (see e.g. pages 232-233). The carob preparation is 80-90% fiber (see e.g. page 232 –Table 1) and therefore would contain 1-15 grams of fiber, as instantly claimed.

Breivik et al. beneficially teach a fatty acid composition which comprises omega-3-fatty acids (see e.g. abstract). Breivik et al. further beneficially teach that the composition contains omega-3 fatty acids, specifically, a combination of 5,8,11,14,17-eicosapentaenoic acid and 4,7,10,13,16,19-docosahexaenoic acid (see e.g. claim 1). It is further disclosed by Breivik et al. that the composition is useful for treatment or prophylaxis of multiple risk factors known for cardiovascular disease, including hypertriglyceridemia (see e.g. col 10, lines 34-39) and that it has been shown that the composition lowers total serum cholesterol significantly (see e.g. col 9, lines 19-24). Please note that the particular source of the n-3- fatty acids instantly claimed would not render the composition unique over the prior art because the structure of the n-3 fatty acid would necessarily be the same if it were indeed an n-3 fatty acid.

McKenney beneficially teaches a number of treatments for hypercholesterolemia, including several cholesterol-reducing active compounds. McKenney beneficially teaches that statins, bile acid resins (bile acid sequestrants), niacin (a nicotinic acid

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derivative), and fibrates are useful in reducing cholesterol (see e.g. 301-304).

McKenney further beneficially teaches that fiber from vegetables and dietary adjuncts such as fiber and stanol/sterol esters can lower LDL cholesterol (see e.g. p. 300), which would read on the instantly claimed phytosterols, plant sterols and cholesterol-reducing plant extracts.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the insoluble fiber containing carob product beneficially taught by Marco et al. with the n-3 fatty acid composition beneficially taught by Breivik et al and any of the cholesterol reducing active compounds beneficially taught by McKenney and well known in the art to obtain a cholesterol lowering agent as instantly claimed. It would have also been obvious to one of ordinary skill in the art at the time the claimed invention was made to provide the carob product in the composition in an amount ranging from 1 to 15 grams. This is particularly true in light of the beneficial teaching of Zunft et al. that administration of 15 grams of carob fiber reduced total and LDL cholesterol levels in test subjects (see e.g. Abstract and entire article). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the instant ingredients for their known benefit- i.e. reducing cholesterol -since each is well known in the art for the same purpose and for the following reasons. It is well known that it is *prima facie* obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose (as well as to use the combination for that purpose). The idea for combining them flows

logically from their having been used individually in the prior art. In re Sussman, 1943 C.D. 518; In re Pinten, 459 F.2d 1053, 173 USPQ 801 (CCPA 1972); In re Susi, 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); In re Crockett, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960). This rejection is based upon the well established proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients. The adjustment of particular conventional working conditions (e.g. the particular result-effective combination of one or more of the instantly claimed agents or the particular amount or form) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Applicants have summarized the invention and the state of the art.

Applicants argue that the cited references, individually, do not teach the instantly claimed invention.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections

are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Applicants argue that Marco et al. merely generally teach that carob fiber of an indeterminate length, when ingested alone, has a hypocholesterol-aemiant effect and that Marco et al. does not teach that the carob fiber has a synergistic cholesterol-reducing effect when it is combined with an n-3 fatty acid and a cholesterol reducing active compound. This is not persuasive, however, as the rejection is based on the combination of the prior art teachings, rather than the teaching of each reference alone. Each of the references teach the cholesterol-reducing ability of the components of the instantly claimed composition. As previously stated, Marco et al. do in fact teach that the carob fiber product has a hypocholesterol-aemiant effect, which can counteract the effects of modern cholesterol-rich diets (see e.g. col 1, lines 34-39). In addition, Applicants argument that the carob fiber taught by Marco et al. is of an indeterminate length is not commensurate in scope with the claims. Nonetheless, Marco et al. do teach that the carob fiber has a particle size of between 4 and .063 mm. This is within the particle size range as instantly disclosed (see e.g. instant Specification – page 8), as .063 mm is 63 μm , which is less than 100 μm , as disclosed. Applicants also argue that Marco et al. do not teach the synergistic cholesterol reducing agent which comprises carob fiber, an n-3 fatty acid and a cholesterol reducing active compound. As previously stated, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the instantly claimed cholesterol

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reducing agents to produce a cholesterol-reducing agent as instantly claimed since each component was known in the art to be effective in reducing cholesterol.

Applicants also argue that Marco et al. do not teach that the carob fiber is administered in a daily dose of 1 to 15 g, as discussed above, this would have been obvious to one of ordinary skill in the art at the time the claimed invention was made based on the beneficial teaching discussed above of Zunft et al.

Applicants argue that Breivik et al. teach that neither DHA or EPA have an effect on blood pressure. This is not commensurate in scope with the claims, as the claims are drawn to a cholesterol-lowering agent. Furthermore, the combined disclosure of the instantly cited references teach a cholesterol-reducing agent, not an agent effective in regulating blood pressure. Applicants also argue that Breivik et al. indicate that DHA alone is ineffective, however, this is not persuasive. Breivik et al. do not indicate that DHA alone is ineffective at reducing cholesterol. Applicants further argue that Breivik et al. do not disclose that cholesterol reduction of at least 10% is achieved when the n-3 fatty acid is DHA alone. This is not persuasive, because as previously stated, Applicants do not have support for this limitation in the Application as originally filed. Furthermore, Applicants use of the term "comprising" suggests that other components may be present in the composition. Thus, the cholesterol-reducing effect of DHA taught by Breivik et al., even if it is combined with another agent, would render obvious the use of DHA in a cholesterol-reducing agent as instantly claimed. Applicants also argue that Breivik et al. do not teach that DHA is administered in an amount ranging from 60mg to

600mg. This is not persuasive, however, as Breivik et al. disclose that capsules intended for administration contain 315 mg of DHA (see e.g. col 11, lines 30-39).

Applicants admit that McKenney teaches that statins, bile acid resins (bile acid sequestrants), niacin (a nicotinic acid derivative), and fibrates are useful in reducing cholesterol. Applicants also admit that McKenney teaches that omega-3 fatty acids and fiber are beneficial for reducing cholesterol. This teaching provides motivation to combine such cholesterol reducing agents with the fatty acid and fiber taught by Marco, Breivik, Zunft. Although Applicants argue that McKenney only teaches that drug combinations provide advantageous results, however, McKenney does teach that combination therapy is useful in reducing cholesterol. Thus, the skilled artisan would be motivated to use a combination therapy. Applicants have also argued that McKenney does not teach the particular fatty acids instantly claimed or the carob product instantly claimed. This is not persuasive because, as previously stated, the combined teachings of the instantly cited references render obvious the instantly claimed invention. Applicants also argue that McKenney does not teach that n-3 fatty acids for use in reducing cholesterol are derived from vegetables or microorganisms, as instantly claimed. This is not persuasive, however, as McKenney is relied upon for the teaching of cholesterol reducing agents such as statins and the motivation to combine them with other cholesterol reducing agents. Breivik et al. teach the instantly claimed fatty acids. The source from which they are derived does not distinguish them from those instantly claimed since they are the same fatty acids.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Conclusion


No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melenie McCormick whose telephone number is (571) 272-8037. The examiner can normally be reached on M-F 7:30am-4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Melenie McCormick
Examiner
Art Unit 1655



CHRISTOPHER R. TATE
PRIMARY EXAMINER